

REMARKS

A. Claim Amendments.

Claims 5, 6, 17, 23, 27, 28 and 29-31 were previously withdrawn as being drawn to non-elected claims. Claim 33 is canceled as depending from a previously withdrawn claim. Claims 24-26 were previously canceled. In anticipation of allowance, the previously withdrawn claims are now cancelled, without prejudice to their later presentation in a divisional application. The claims pending after amendment are therefore Claims 1-4, 7-16, 18-22, 24-26, and 32.

Claim 1 is amended to recite that not only may the composition of the invention be removed within an hour of administration, up to 100% of lice will have died within 24 hours of administration. Support for the claim language is found in the Specification at, for example, paragraphs 0036 and 0039. No new matter is added by this amendment, which places the claims in condition for allowance. Entry thereof is therefore requested.

B. Response to Rejection under Section 102(a) & (e), based on Pearlman.

Claims 1-4, 7, 12-15, 18, 32 and 33 stand rejected under Section 102(a) and (e) based on Pearlman, US Patent No. 6,303,581, on the basis that Pearlman discloses that "6 seconds to 4 hours suffices to remove the composition." (Office Action at page 4, sixth paragraph, citing to Pearlman at Col. 13, lines 12-20 and Col. 15, "top"). Applicant respectfully disagrees.

As discussed in the prior amendment, the compositions of the present invention kill ectoparasites, whereas those of Pearlman principally act to immobilize lice to facilitate their removal from the scalp. To that end, Pearlman requires that the compositions applied dry onto treated lice (*see*, e.g., column 7, lines 61-62). Eventually, the treated lice may suffocate, but the rest will be removed by combing (column 8, lines 28-36).

As explained in the prior amendment, the compositions of the present invention do not dry within the hour time frame recited in the claims (see, e.g., the study of record performed in 2000 at Harvard, Spielman, <http://www.hsph.harvard.edu/headlice.html>, 2000: more than 1 hour is required for lice to suffocate in an oil-based agent; and, Murphy, et al., US Pat. 4,414,200: cyclodimethicone requires as long as 72 hours to fully dry at 25-30°C, even when admixed with isopropyl myristate [see, Col. 3, lines 40-44 and Col. 4, lines 32-65]).

Drying isn't necessary, because ectoparasites are killed by the invention within as little as 10 minutes (see, e.g., Example 3—lice morbidity was up to 100% after an application of only 10 minutes, after which the composition was removed and morbidity determined at 24 hours). As described in the Declaration of Dr. William Campbell at paragraph 4, it is believed that the mechanism of action is through dehydration.

In contrast, Pearlman teaches away from the use of such *pediculocidal* compositions; i.e., those that “disrupt metabolic or physiologic pathways” (Pearlman, column 7, line 62 through column 8, line 5). Rather, Pearlman’s composition induces an “immersion reflex” in the lice which merely immobilizes them. Although one could remove the Pearlman compositions in “6 seconds to 4 hours” as contended in the Office Action, doing so would not cause the treated lice to die—that effect takes at least an overnight application to provide without drying, and 8 hours to provide with drying:

CETAPHIL® Cleanser has the ability rapidly to trigger  
the “immersion reflex” in head lice. Both in vivo and in  
vitro, lice coated in CETAPHIL® Cleanser became immo-  
bilized within 6 seconds. On the patients’ scalp, the lice

became totally immobilized, floating on the scalp in the Cleanser. They were easily removed by forceps without any effort to escape or to grasp the hair shaft to stay in place. Under the microscope, they were immobile, did not respond to being touched, and lost their normally visible gut motility. They remained immobilized as long as they were in the Cleanser. This phenomenon was observed for periods ranging from 6 seconds to 4 hours. At any point prior to drying the cleanser, the louse could be removed from the Cleanser and usually awakened and resumed crawling. When immersed overnight in CETAPHIL® Cleanser (12 hours) the lice died.

When CETAPHIL® Cleanser was dried onto lice (6 lice tested), the lice remained immobile. When the dried agent was removed by redissolving it in water after 4 hours of contact, the lice recovered and regained mobility. When left on the lice for more than 8 hours before redissolving, the lice died.

*Pearlman, '581, at Col. 14, line 64 to Col. 15, line 18.*

Therefore, Pearlman does not teach or suggest means for killing lice within 24 hours of application of the compositions of the invention for less than an hour, during which time the compositions do not dry onto the lice (independent Claim 1), nor any means for killing lice with such compositions by stripping the waxy cuticle therefrom (independent Claim 12).

Based on all the foregoing, it is submitted that Pearlman does not anticipate or render the invention of Claims 1-4, 7, 12-15, 18, 32 or 33 obvious. Reconsideration and withdrawal of the rejection under Section 102(a) and/or (e) is therefore requested.

C. Response to Comments Concerning Claims 23, 27 and 28.

The Office Action states that "Claims 23, 27 and 28 require another active, contrary to independent claims." (Action at page 2). However, no related rejection of, or statutory objection to, these claims is set forth in the Action. Nonetheless, Applicants respectfully suggest that the comment is moot, as Claims 23, 27 and 29 were previously withdrawn as being drawn to a non-elected invention.

The Office Action also states that "Claims 29-31 are not in accord with allowed independent claims." Again, no related rejection of, or statutory objection to, these claims is set forth in the Action. Further, no claims are allowed. Applicants therefore cannot respond to the comment but note that, in any event, it appears to be moot as Claims 29-31 were previously withdrawn as drawn to a non-elected invention.

D. Cancellation of Non-Elected Claims

Applicants respectfully submit that the claims are now in condition for allowance, for all the reasons stated above. In anticipation of allowance, the previously withdrawn claims are now cancelled, without prejudice to their later presentation in a divisional application.

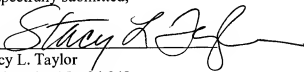
CONCLUSION

All of the pending claims (1-4, 7-16, 18-22, 24-26, and 32) are believed to be in condition for allowance. Reconsideration of the claims rejections and objections is therefore requested as outlined above.

No fee is believed to be due in connection with filing this paper. However, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

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Stacy L. Taylor  
Registration No. 34,842  
Telephone: (858) 677-1423  
Facsimile: (858) 677-1465

DLA PIPER US LLP  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer Number 28213**